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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

1st named inventor:	Sheng-Ping Zhong
Application No.	09/993,907
Filed:	November 27, 2001
Title:	IMPLANTABLE OR INSERTABLE MEDICAL DEVICES VISIBLE UNDER MAGNETIC RESONANCE IMAGING
Art Unit:	3737
Examiner:	Ruth S. Smith
Confirmation No.:	7678
Docket No.:	01-286

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF

Dear Sir:

This is a reply pursuant to 37 C.F.R. §41.41 and MPEP 1208 in response to the Examiner's Answer mailed on April 24, 2006 in the appeal from the Examiner's decision dated July 14, 2005, finally rejecting Appellants Claims 1, 3-8, 10-12, 15-38 and 69. This Reply Brief is filed within two months of the Examiner's Answer mailed April 24, 2006.

I. REAL PARTY IN INTEREST

The statement contained in the Appeal Brief identifying the real party in interest is incorporated herein by this reference.

II. RELATED APPEALS AND INTERFERENCES

The statement contained in the Appeal Brief indicating that there are no related appeals or interferences for this application or any related co-pending applications is incorporated herein by reference.

IIII. STATUS OF CLAIMS

The presently pending claims are claims 1, 3-8, 10-12, 15-38 and 69. Claims 2, 9, 13, 14, 42, and 45 have been cancelled. Claims 39-41, 43, 44 and 46-68 have been withdrawn from consideration pursuant to a requirement for restriction. Claims 1, 3-8, 10-12, 15-38 and 69 are rejected. A copy of claims 1, 3-8, 10-12, 15-38 and 69 is provided in the attached Claims Appendix.

IV. STATUS OF AMENDMENTS

The statement contained in the Appeal Brief indicating the status of amendments is incorporated herein by this reference.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The summary of the claimed subject matter contained in the Appeal Brief is incorporated herein by this reference and adequately describes the claimed subject matter on appeal.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The following grounds of rejection are presented for review:

Claims 1, 3-5, 30 and 35 stand finally rejected under 35 U.S.C (102 b) as being anticipated by DiCosmo et al. US 6,475,516 (DiCosmo).

Claims 1, 3-7, 30 and 35 stand finally rejected under 35 U.S.C. 102(b) as being anticipated by Whitbourne US 5,331,027.

Claims 1, 3-5, 10, 11, 15-22, 28-31 and 35 stand finally rejected under 35 U.S.C. 102(b) as being anticipated by Weissleder US 5,514,379.

Claims 6-8 stand finally rejected under 35 U.S.C. 103(a) as being unpatentable over Weissleder in view of Michaels US 6,112,908.

Claim 12 stands finally rejected under 35 U.S.C. 103(a) as being unpatentable over Weissleder in view of Klaveness et al. US 6,610,269 (Klaveness).

Claim 23 stands finally rejected under 35 U. S. C. 103(a) as being unpatentable over Weissleder in view of Peng et al. US 2002/0061871 (Peng).

Claims 24-27, 32 and 33 stand finally rejected under 35 U.S.C. 103(a) as being unpatentable over Weissleder in view of Cleary et al. US 2003/0170308 (Cleary).

Claims 34, 36-38 and 69 stand finally rejected under 36 U.S.C. 103(a) as being unpatentable over Weissleder.

VII. ARGUMENT

Appellant acknowledges the Examiner's Answer mailed April 24, 2006. The argumentation in the Examiner's Answer essentially the same as the argumentation in the final rejection, although the following was added to the Response to Argument in the Answer: "Furthermore, it is respectfully submitted a hydrogel coating will inherently, based upon its known properties and based upon the known manner in which MRI operates, render the device visible under MRI when placed in a patent."

In this regard, and as noted from Appellant's Argument in the Appeal Brief, the examiner is required to provide evidence or a clear explanation in support of assertions of this nature and she has not done so:

> "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)....

MPEP 2112 IV.

As also noted from Appellant's Argument in the Appeal Brief, a holding of inherency must flow as a necessary conclusion from the prior art, not simply a possible one.

> The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because

> inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 U.S.P.Q. 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 U.S.P.Q.2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted)...

MPEP 2112 IV.

The limitation of claim 1 "said hydrogel polymer is adapted by cross-linking said hydrogel polymer to a degree sufficient to render said medical device visible under magnetic resonance imaging" cannot be said to flow as a necessary conclusion from the prior art.

Furthermore, even assuming *arguendo* that a particular cross-linked gel referred to by the examiner is MRI detectable, the reference would still not be an anticipation. Within product claim 1 is found a limitation that "visibility of detectable species associated with said hydrogel polymer to magnetic resonance imaging is modified by varying the degree of said cross-linking." The concept embodied by that limitation is lacking from the references cited by the examiner.

The remainder of the Argument contained in the Appeal Brief is incorporated herein by reference.

CONCLUSION

It is respectfully submitted that reversal of the rejections of record is in order.

FEES

The Office is authorized to charge any fees due and owing in respect to the filing of this paper to deposit account number 50-1047.

Respectfully submitted,

David B. Bonham Reg. No. 34,297

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Marjorie Scariati

(Printed Name of Person Mailing Correspondence)

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(Signature)

VIII. CLAIMS APPENDIX

1. (Previously Presented) An implantable or insertable medical device comprising:

(a) a substrate;

(b) a hydrogel polymer coating at least a portion of the surface of the substrate, wherein said hydrogel polymer is adapted by cross-linking said hydrogel polymer to a degree sufficient to render said medical device visible under magnetic resonance imaging upon insertion or implantation of said medical device into a patient, and wherein visibility of detectable species associated with said hydrogel polymer to magnetic resonance imaging is modified by varying the degree of said cross-linking.

3. (Original) The implantable or insertable medical device of claim 1, wherein said hydrogel polymer is adapted by decreasing the relaxation time of said detectable species associated with said hydrogel polymer relative to the relaxation time of detectable species in the environment surrounding the device.

4. (Original) The implantable or insertable medical device of claim 3, wherein said detectable species associated with said hydrogel polymer comprise detectable protons.

5. (Original) The implantable or insertable medical device of claim 4, wherein water molecules associated with said hydrogel polymer comprise said detectable protons.

6. (Original) The implantable or insertable medical device of claim 4, wherein hydroxyl groups associated with said hydrogel polymer comprise said detectable protons.

7. (Original) The implantable or insertable medical device of claim 6, wherein a compound dispersed within said hydrogel polymer comprises said hydroxyl groups.

8. (Original) The implantable or insertable medical device of claim 7, wherein said compound dispersed with said hydrogel polymer comprises glycerin.

10. (Original) The implantable or insertable medical device of claim 1, wherein said hydrogel polymer is adapted by incorporating paramagnetic ions in said hydrogel polymer.

11. (Previously Presented) The implantable or insertable medical device of claim 1, wherein said hydrogel polymer is adapted by incorporating paramagnetic particles in said hydrogel polymer.

12. (Original) The implantable or insertable medical device or claim 11, wherein said paramagnetic particles comprise starch-coated iron oxide particles.

15. (Original) The implantable or insertable medical device of claim 10 wherein said hydrogel polymer comprises paramagnetic ion chelating groups.

16. (Original) The implantable or insertable medical device of claim 15, wherein said paramagnetic ion chelating groups are covalently bonded to the hydrogel polymer.

17. (Original) The implantable or insertable medical device of claim 10, wherein said hydrogel polymer comprises a paramagnetic ion chelation complex.

18. (Original) The implantable or insertable medical device of claim 17, wherein said paramagnetic ion chelation complex is covalently bonded to said hydrogel polymer.

19. (Original) The implantable or insertable medical device of claim 10, wherein said paramagnetic ions are selected from the group of chromium (III), manganese (II), iron (III), iron (II), cobalt (II), copper (II), nickel (II), praesodymium (III), neodymium (III), samarium (III), ytterbium (III), gadolinium (III), terbium (III), dysprosium (III), holmium (III) and erbium (III).

20. (Original) The implantable or insertable medical device of claim 19 wherein said paramagnetic ions comprise gadolinium (III).

21. (Original) The implantable or insertable medical device of claim 15, wherein said paramagnetic ion chelating groups comprise organic acid functional groups.

22. (Original) The implantable or insertable medical device of claim 15, wherein said paramagnetic ion chelating groups comprise carboxyl groups.

23. (Original) The implantable or insertable medical device of claim 15, wherein said paramagnetic ion chelating groups comprise aminopolycarboxylic acid groups.

24. (Original) The implantable or insertable medical device of claim 22, wherein said hydrogel polymer comprises substituted or unsubstituted acrylic acid monomer units.

25. (Original) The implantable or insertable medical device of claim 24, wherein said hydrogel polymer comprises polyacrylic acid.

26. (Original) The implantable or insertable medical device of claim 24, wherein said hydrogel polymer further comprises substituted or unsubstituted acrylamide monomer units.

27. (Original) The implantable or insertable medical device of claim 26, wherein said hydrogel polymer is a copolymer of acrylic acid and acrylamide.

28. (Original) The implantable or insertable medical device of claim 17, wherein said paramagnetic ion chelation complex is selected from the group consisting of diethylene triamine pentaacetic acid (DTPA), tetraazacyclododecane tetraacetic acid (DOTA), and tetraazacyclo tetradecane tetraacetic acid (TETA).

29. (Original) The implantable or insertable medical device of claim 28, wherein said paramagnetic chelation complex comprises diethylenetriamine pentaacetic acid (DTPA).

30. (Original) The implantable or insertable medical device of claim 1, wherein said hydrogel polymer is selected from the group consisting of polyacrylates; poly(acrylic acid);

poly(methacrylic acid); polyacrylamides; poly(N-alkylacrylamides); polyalkylene oxides; poly(ethylene oxide); poly(propylene) oxide; poly(vinyl alcohol); polyvinyl aromatics; poly(vinylpyrrolidone); poly(ethyleneimine); polyethylene amine; polyacrylonitrile; polyvinyl sulfonic acid; polyamides; poly(L-lysine); hydrophilic polyurethanes; maleic anhydride polymers; proteins; collagen; cellulosic polymers; methyl cellulose; carboxymethyl cellulose; dextran; carboxymethyl dextran; modified dextran; alginates; alginic acid; pectinic acid; hyaluronic acid; chitin; pullulan; gelatin; gellan; xanthan; carboxymethyl starch; chondroitin sulfate; guar; starch; and copolymers, mixtures and derivatives thereof.

31. (Original) The implantable or insertable medical device of claim 1, wherein said hydrogel polymer is selected from the group consisting of poly(acrylic acid); polyacrylamide; poly(N-alkylacrylamide); copolymers of acrylic acid and acrylamide; poly(ethylene oxide); poly(propylene oxide); copolymers of ethylene oxide and propylene oxide; hyaluronic acid; and poly(L-lysine).

32. (Original) The implantable or insertable medical device of claim 31, wherein said hydrogel polymer comprises poly(acrylic acid).

33. (Original) The implantable or insertable medical device of claim 31, wherein said hydrogel polymer comprises a copolymer of acrylic acid and acrylamide.

34. (Original) The implantable or insertable medical device of claim 1, further comprising a lubricious coating layer disposed on said hydrogel polymer.

35. (Original) The implantable or insertable medical device of claim 1, wherein said medical device is selected from the group consisting of catheters, guide wires, balloons and stents.

36. (Original) The implantable or insertable medical device of claim 35, wherein said catheter is a neuro-interventional microcatheter.

37. (Original) The implantable or insertable medical device of claim 35, wherein the stent is selected from the group consisting of endovascular, biliary, tracheal, gastrointestinal, urethral, ureteral and esophageal stents.

38. (Original) The implantable or insertable medical device of claim 37, wherein the stent is a coronary stent.

69. (Previously Presented) The implantable or insertable medical device of claim 1 wherein a primer coating to enhance adherence of said hydrogel polymer (b) to said substrate (a) is applied to said substrate prior to coating with said hydrogel polymer.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.